Description

HEALING SHOE OR SANDAL

BACKGROUND DESCRIPTION OF THE INVENTION

Field of the Invention

[01] The present invention pertains to a shoe or sandal specifically designed to aid in the offloading, or reducing weight or pressure, from a specific area of the foot. The shoe or sandal, and specifically the insole and outer covering of the shoe upper, are designed to be altered by or under the direction of the health care provider to either offload weight from the bottom of the foot or to remove or reduce pressure from the sides, top or other specific areas of the foot.

[02] The incidence of foot ulcers, infections and deformities of the feet has become an increasing problem as the life expectancy of patients with diabetes and other chronic diseases increase. The cost of treatment of these complex foot problems has escalated to the point that the Center for Disease Control and others in the health delivery system are placing a special emphasis on finding more effective ways of treating these problems. Patients with circulatory problems, diabetes, AIDS, arthritis neuropathies and other debilitating diseases experience complications that lead to increased deformities in the feet subjecting the deformed areas to increased pressures and friction. Spinal cord injuries and other injuries to the back and lower extremities may cause neuropathies that in turn produce deformities in the toes and feet with a loss of feeling causing more complications to develop. Chemically induced neuropathy from chemotherapy, alcohol, drug abuse, etc., may also lead to ulcerations and lesions of the feet that require special care. All of these problems are exacerbated by weight bearing pressure or friction from conventional shoes. Regardless of how aggressive the treatment plan, the use of expensive antibiotics, local wound care, surgery etc., healing is delayed and the lesions and infections reoccur unless effective measures are taken to redistribute weight reducing pressure and friction from the involved foot lesions.

Description of the Related Art

[03] Orthotics (othopedic inserts) for supporting certain aspects of the human foot are well known in the field of podiatric medicine. However, orthotics can produce added pressure on the supported areas and cause rubbing which may lead to blistering or other ailments, complicating the above-described problems. Orthotics require additional space when used in conjunction with standard insoles and may even require extra space when comprised in a customized insole. Thus, when used in normal mass market shoes, orthotics can also cause rubbing on opposite surfaces of the foot, due to reduced clearance between foot and the shoe upper. Othopedic shoes such as those manufactured by Markell ® and others provide extra depth to accommodate foot deformities and/or orthotics, but have an extremely awkward appearance, generally having a much higher profile (taller appearance) than normal mass-market shoes, and can be unstable when multiple inserts are used.

[04] The wound care shoe system is designed to produce a foot friendly environment where pressure and friction are reduced allowing healing to take place and to reduce the incidence of reoccurrence of a lesion. The invention provides an easy to use healing shoe or sandal and an effective method to offload weight from a particular area of the plantar aspect (bottom) of the human foot by using alterable insoles or insole layers of varying densities and degrees of firmness which fit into an area surrounded by a circumferential counter, in order to hold the insole layers in position. This creates a low profile more stable shoe than prior art extra depth shoes. The outer covering of the upper is also constructed of materials that can be cut out or heat molded or otherwise altered to reduce friction and/or pressure from the non-weight bearing areas of the foot.

SUMMARY OF THE INVENTION

[05] The above and other objects of the invention, which will become apparent hereinafter, are achieved by the provision of an adjustable sandal or shoe with the

upper constructed of a combination outer cover, preferably of leather, with an inner liner preferably of EVA or Plastizote, or similar material. This upper permits small portions of the outer cover over a lesion or bony prominence to be cut away leaving the underlying moldable liner of EVA for protection without destroying the integrity of the shoe. This removes the friction and pressure from the area over the lesion permitting faster healing. An out sole, including a base portion having a rocker bottom and a circumferential counter are molded in one piece providing a cavity with space for the various layers of insole material as well as stabilizing the insoles within the cavity of the outsole. The insoles are fabricated of soft, medium and firm density EVA or other suitable materials that mold to the foot. Certain sections of the insoles can be ground down or cut away, to redistribute weight away from a lesion or areas of excessive pressure. The insoles are either heat or pressure moldable. A fitting marker is also located on the medial side of the out sole in order to aid the health care provider in proper shoe fitting.

BRIEF DESCRIPTION OF THE DRAWINGS

[06] Fig. 1 is a top and front elevation of the wound care sandal or shoe forming a preferred embodiment.

[07] Fig. 2. is a medial side elevation of the wound care shoe illustrating a fitting marker molded on the side of the out sole, and an upper composed of an outer covering and a lining with the outer covering cut away to expose the lining and remove pressure from an ulcer or other lesion while the underlying soft lining remains in place to provide protection while reducing pressure over the lesion. Fig. 2 also illustrates a rocker bottom out sole which improves ambulation while reducing weight bearing pressure from the heel and forefoot as well as reducing friction within the shoe from foot movement, and a foam-padded collar designed to reduce pressure and provide comfortable fit around the heel and ankle.

[08] Fig. 3 is a cut-away or cross section of the foot and healing shoe showing the circumferential counter extending upward from the sole, and four (4) layers of multi-density insoles, as well as the layer of polywood and a metatarsal shank.

[09] Fig. 4 is a longitudinal cross section of the wound care shoe illustrating the insole layers, metatarsal shank within the outsole and circumferential counter.

[10] Fig. 5A. is a cross section of a human foot illustrating the metatarsals and phalanges of the foot.

[11] Fig. 5B. is a cross section of the shoe and foot at the metatarsal head level illustrating an altered insole to remove pressure from a plantar lesion of the foot.

[12] Fig. 6. is a side elevation of the wound care shoe showing the opposite side of the wound care shoe from Fig. 2.

[13] Fig. 7 illustrates the general shape of the out sole in a plantar aspect of the human foot, in conjunction with table 2.

[14] Fig. 8 illustrates the arrangement of the insole layers of the wound care shoe for treating a specific type of ailment.

[15] Fig. 9 illustrates the arrangement of the insole layers of the wound care shoe for treating an alternate specific type of ailment.

[16] Fig. 10 illustrates a preferred cut out of at least one insole layer of the wound care shoe for treating a wound.

[17] Fig. 11 illustrates the arrangement of the insole layers of the wound care shoe for treating another alternate type of ailment.

[18] Fig. 12 illustrates the arrangement of the insole layers of the wound care shoe for treating yet another specific type of ailment.

[19] Fig. 13 illustrates the arrangement of the insole layers of the wound care shoe for treating still another type of ailment.

DETAILED DESCRIPTION OF THE INVENTION

[20] A sandal or shoe 10 for use by health care professionals in the treatment of infections, ulcerations, and other conditions of the foot, due to complications of diabetes or other medical conditions such as rheumatoid arthritis, vascular conditions,

neuropathy, or due to trauma of the feet from a variety of causes, in which it is desirable to redistribute weight away from the infected or traumatized area to be treated. The design (as shown in Fig. 2) of the sandal or shoe 10 includes a molded out sole 100, an upper portion 300, and an adjustable insole 500.

[21] The shoe is designed to accommodate the use of layers of various insole materials generally of a microcellular foam, but not limited to such, including without limitation Plastizote (Plastizote is a medically inert, high density polyethylene closed cell foam having excellent memory and impact absorption properties), Ethylene Vinyl Acetate (E V A), Poron (Poron is a impact absorbing open cell cellular urethane foam product), or similar material, to offload specific areas of the foot in order to promote healing of fractures, ulcers or infections when healing may be delayed by weight bearing pressure on the lesion.

[22] The molded out sole may be constructed from any suitable material including without limitation Ethylene Vinyl Acetate (E V A); polyurethane or other plastic or thermoplastic; rubber, including thermoplastic rubber (TPR), styrene butadiene rubber and natural rubber; or combination thereof. The out sole includes a base portion and a circumferential counter portion. The circumferential counter is molded as a part of the out sole extending completely around an upper portion of the circumference of the out sole. The circumferential counter extends upward from the upper surface of the base portion of the out sole, over an upper portion of the shoe from ¼ to 1 inch.

[23] The circumferential counter extends around the circumference of the top portion of the out sole and forms an opening, cavity, depression or pocket that allows the upper portion of the shoe to be conjoined with or counter sunk into the out sole. This permits extra depth in the upper portion of the shoe in which a variety of insole layers can be placed. The shoe, despite the extra depth, will have a lower profile than the prior art because the extra depth is within the out sole rather than the shoe upper. The cavity within the out sole of the shoe will provide a lower profile more like a conventional shoe while at the same time providing the extra room necessary to accommodate the multi-density insoles or insole layers.

[24] Various types and thickness of insole material such as EVA can be placed in the cavity portion of the out sole of the shoe and may be altered by either grinding or cutting away particular sections to remove weight or provide offloading of the specific area of the foot being treated. The cavity in the out sole permits the application of insole material below the level of the top of the circumferential counter thereby providing greater stability for the (human) foot and preventing the layered insole material from shifting as occurs in conventional shoes and particularly conventional extra depth shoes, if a layered insole is placed in a conventional extra depth shoe where the extra depth (and therefore the layered insole material) is above the out sole level.

[25] The upper surface of the base portion of the out sole (inside the cavity) has a small rectangular opening or trough to accommodate a plastic or metal shank (metatarsal shank). The metatarsal shank (155), as shown in Fig. 4, begins at a location corresponding approximately with the distal 1/3 of the metatarsals (710, as shown in Fig. 5) of a human foot (700) encased by the shoe or sandal as viewed from the plantar aspect (near the axial center of the outsole of the shoe), and extends distally (axially) across the metatarsal-phalangel joints (phalanges (750) shown in Fig. 5) of the foot (700) as viewed from the plantar aspect. The metatarsal shank reduces motion in the shoe and in the corresponding portion of the foot, as well as adds strength to the out sole.

[26] With reference to Fig. 1. the upper 300 of the shoe 10 is closed around the human foot 700 (as shown in Fig. 5) by overlapping inner 310 and outer 320 flaps secured by any of fastening means including but not limited to: buttons and corresponding button holes, snaps, eyelet holes with interconnecting laces, or patches of a hook and loop material (e.g., VELCO ®). An additional and preferred alternative is interconnection of the overlapping inner 310 and outer 320 flaps using hook and loop straps (generally, 380). One strap closes in front of the ankle (a first or ankle strap 482) to lock the heel in position to reduce slipping of the heel in the shoe. The

second (forefoot) strap 484 fastens over the forefoot to hold this portion of the foot in place. Each flap includes a first (ankle) ring 420 corresponding to the ankle strap 482 and a second (forefoot) ring 440 corresponding with the forefoot strap 484. The ankle 420 and forefoot 440 rings are positioned directly across (transversely) from one another and the respective strap (482 or 484) is threaded through the respective pair of rings (420 or 440) and secured, thereby securing the inner 310 and outer 320 flaps in place by applied pressure and tension (between the ring pairs). Additionally, the straps 380 may be stitched at intervals 484, to permit shortening of the straps as edema subsides or the bulk of bandages are reduced. The straps are cut in front of the appropriate stitch line 488 to prevent fraying of the straps.

[27] As illustrated in Fig. 2, the shoe upper 300 is constructed of an outer covering 340 of leather, canvas, nylon mesh or other suitable material with an inner lining 350 of EVA or soft foam material that can be easily separated from the outer covering. The inner lining 350 reduces friction against the non-weight bearing surfaces of the foot while providing increased comfort. This construction allows the removal of a specific section of the outer covering (as shown at 390 in Fig. 2) over a pressure point or lesion leaving the soft, heat or pressure moldable inner lining 350 (EVA), in place over the ulcer or prominence for protection. There is also a foam-padded collar 370 around the heel and ankle portion (heel portion or heel counter 360) of the shoe or sandal 10, to prevent pressure from the outer covering 340 material and reduce heel slippage. To assist the health care provider in proper fitting of the shoes a fitting marker 270 is molded into the medial side of the out sole 100. The end of the first metatarsal 710 generally should extend slightly in front of the fitting marker 270 to reduce pressure under the metatarsal heads 720 (as shown in Fig. 5) and permit the rocker bottom out sole 160 (as discussed below) to perform properly.

[28] With reference to Fig. 3, the molded out sole 100 of the shoe or sandal 10 is designed with a circumferential counter 120 that extends ¼ to 1 inch onto the shoe upper 300 above the upper surface 130 of a base portion 110 of the outsole 100. Imbedded in the base portion 110 of the rocker bottom out sole 100 is the metatarsal

shank 155, constructed of metal, plastic or other suitable material that begins near the distal 1/3 of the metatarsals (710, as shown in Fig. 5) extending across the metatarsal-phalangel joints to control motion in that portion of the foot. This out sole 100 and the circumferential counter 120, are molded in one piece and designed to add stability to the foot while providing space for the insole 500 including insole layers (generally, 520) of insole material (individually 600, 620, 640, 660), within the out sole cavity 140 to prevent shifting of the insole layers 520 and permit offloading of specific areas of the foot.

[29] The insole layers 600, 620, 640 and 660 are constructed of Ethyl Vinyl Acetate (EVA) or other suitable material of varying densities. The cavity (pocket) 140 formed by the circumferential counter 120 also presents a lower profile in that the insole layers 520 are confined within the molded out sole 100 below the level of the upper portion of the shoe rather than in the shoe upper itself. The poly-wood layer 680, forming the foundation of the insole 500, is about 2mm thick. The durometer (hardness) or relative density of the insole layers 600, 620, 640 and 660 are preferably within 5 degrees of the following example of the preferred embodiment but are not in anyway limited thereto.

Table 1

Insoles Layer	Durometer	Thickness	Material
600	26	1/4 in.	soft EVA or Plastizote
620	29	1/8 in.	high-density foam/soft Poron
640	42	1/4 in.	medium-density foam/ EVA or Plastizote
660	50	1/4 in.	firm-density foam/ EVA or Plastizote

[30] With reference to Fig. 4, the layers 520 of insole material 600, 620, 640 and 660 and the inventive out sole 100 provide the extra height (depth) necessary (as if these components were actually a part of the out sole) to create a rocker bottom sole.

The rocker bottom 160 of the out sole 100 permits easy ambulation while at the same time allowing the patient to stand on the flat stable mid section 262 of the rocker bottom 160 of the out sole 100. The rocker apex 267 of the rocker bottom 160 of the out sole 100 is located at (just below) the fitting marker 270 or just proximal to the metatarsal heads (720, see Fig. 5 A & B) to reduce pressure from the metatarsal heads 720 and then tapers off toward the toe of the out sole in the toe section 261. The heel section 263 of the rocker bottom 160 of the out sole 100 is tapered at an oblique angle from mid-section 262 to the rear of the rocker bottom 160 of the out sole 100 in a manner to cause heel strike about mid-heel at the oblique angle 268 between the heel section 263 and mid section 262. The rocker bottom 160 combined with the metal or plastic metatarsal shank 155, allows the patient to ambulate comfortably while reducing motion of the foot thereby reducing the friction caused by the foot movement within the shoe.

[31] Referring now to Fig. 5 A & B, the shoe upper 300 having an inner lining 350 and an outer covering 340, as well as the insole layers 520 (600, 620, 640 and 660) of EVA, Poron and or other suitable material are designed to be altered as shown at 550 (see Fig. 2 at 390 for alteration of the upper), by or under the direction of the health care provider to offload weight from a specific area 770 of the foot. While the manner in which the insoles or shoe need to be altered is a clinical judgment for the health care provider, a method for altering the shoe is described hereinafter.

[32] Non-weight bearing ulcers generally occur over the posterior, medial or lateral aspect (on the top (dorsal) portion of the foot as opposed to the plantar aspect. For non-weight bearing ulcerations, regardless of grade (severity), the external cover of the shoe only is removed (see Fig. 2, element 390) leaving the soft inner lining intact to protect the lesion being treated and reduce the occurrence of window edema. Air holes may be added to the outer covering 340 in order to facilitate outer covering removal in those areas where ulcers are most likely to occur. Where such air holes are provided, the health care professional optimally should pass a small, blunt object (e.g., a large paperclip) from one air hole to the adjacent air hole in the outer covering,

being careful not the penetrate the inner lining in order to remove a particular region of the outer covering without damaging the inner lining. Alternately, using a sharp instrument, the health care professional should cut away the portion of the outer covering surrounding (directly above) the lesion to be treated or between the air holes nearest the lesion in order to remove the required amount of outer covering. The initial cut should be below the level of the top of the area being removed (dorsally). A flat instrument or tongue depressor may then be inserted between the covering and the lining to prevent accidental cutting or damage to the lining when the covering is cut away. Insole layers 520 should optimally be arranged as indicated by Fig. 8 when no open ulcers are present. Should the ulcer or inflammation extend to the plantar surface of the foot, the insoles should be altered in the same manner as described below for the treatment of plantar (weight-bearing) ulcers.

[33] When treatment of weight-bearing ulcers of grade 0 and 1 on the Wagner Scale on the plantar surface of the foot is required, the insole layers 520 optimally should be placed in the order as indicated in Fig. 9. Using a sharp instrument such as a scalpel or utility knife, the health care professional should cut away an oval area (area to be removed 550) of the medium density insole layer 640 directly under the ulcer as shown in Fig. 5 B and Fig. 9. The health care professional should skive the edges to an angle of approximately 30° so that the opening farther away from the foot is slightly larger than the opening nearer the plantar surface of the foot. The oval relief area should be approximately 0.5 cm larger than the ulcer and extend distally 1.25 cm as shown in Fig 10. A hard, smooth-cutting surface should be used to obtain more accurate and safe cutting results. After the wound has closed, the insole layers should be rearranged as indicated in Fig 11. The shoe can then be used as a household ambulation slipper.

[34] When treatment of weight-bearing ulcers of grade 2 and above on the Wagner Scale on the plantar surface of the foot is required, the insole layers 520 optimally should be placed in the order as indicated in Fig. 12. Using a sharp instrument such as a scalpel or utility knife, the health care professional should cut away an oval area

550 of the medium density insole layer 640 and the firm density insole layer 660 directly under the ulcer as shown in Figs. 5 (showing only the removal of medium density insole layer 640) and 12. The oval relief area should be approximately 0.5 cm larger than the ulcer and extend distally 1.25 cm as described previously with respect to Fig. 10. When the oval area is cut away from the medium density insole layer, the firm density insole layer or both, the opening in the insole should be slightly larger on the bottom (further from the wound) than the top (nearer the wound) in order to minimize pressure and shear to the ulcer margin. After the wound has closed, the insole layers should be rearranged as indicated in Fig. 13. The shoe can then be used as a household ambulation slipper.

[35] Proper fitting of the Wound Care shoe is essential for optimal results. To this end, the fitting marker 270 as shown in Fig 2 is molded into the out sole 100 to assist in proper fitting. The head of the first metatarsal (720 in Fig. 5 A & B) should be positioned such that it is slightly in front of the fitting marker 270 to ensure that the other metatarsal heads are just in front of the high point (rocker apex 267) of the rocker bottom 160 of the out sole 100 to reduce the weight-bearing load on the metatarsal heads and forefoot.

[36] Additionally, a variety of out sole dimensions are contemplated in order to accommodate a wide variety of foot shapes and sizes, as illustrated in Fig. 7 and described in table 2, below. All dimensions are in centimeters (cm).

Table 2

	Out Sole Dimensions		
	A	**B**	**C**
Small	26.00	9.25	6.25
Medium	27.00	10.25	7.00
Large	28.25	10.50	7.50
X-Large	30.50	11.00	7.50
XX-Large	32.00	11.25	7.75

[37] While the present invention and method for using same has been described using specific terms and preferred embodiments, such description is for illustrative purposes only, and it is understood that changes and variations may be made by one skilled in the art without deviating from the broad principles and teachings of the present invention which shall be limited solely by the scope of the claims appended hereto.